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EXAMINER
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FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/806,915

Applicant(s)

NICOL ET AL.

Examiner

Blessing M. Fubara

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-25 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 and 28-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9 and 10. 6) ☐ Other: .

### **DETAILED ACTION**

Examiner acknowledges receipt of response to notification of missing requirement, petition for extension of time and preliminary amendment A filed 11/13/01, request for receipt of CFR and IDS filed 11/01/02 and supplemental IDS filed 12/05/02. Claims 1-25 and 28-30 are pending.

#### ***Specification***

This application is a 371 of PCT/GB99/03288 filed 10/06/1999. Applicants are required to present an amendment to the specification instructing the insertion of --- This application is a 371 of PCT/GB99/03288 filed 10/06/1999--- on page 1 of the specification, between the title and line 5.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 2, 11, 24 and 25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating animal stereotypy, does not reasonably provide enablement for preventing stereotypy. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

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The following Wands factors are considered:

1. The quantity of experimentation necessary

The example in the specification took animals that have been observed to exhibit crib-biting behavior, fed said animals with the composition comprising fiber, oil and antacid and observed the behavior of the said animals. However, the example failed to study animals that have not started to show crib-biting behavior. The quantity of experimentation would be unreasonable and of undue burden to one of ordinary skill or one of skill in the art to perform the test with animals that have not been observed to exhibit crib-biting behavior since the tests were conducted with animals that have shown crib-biting behavior.

2. The amount of direction or guidance presented

The guidance or direction provided is directed to minimizing or treating crib-biting since that animals recruited into the study had started crib-biting. There is no guidance given for preventing crib-biting behavior.

3. The predictability or unpredictability

Exemplification was given only with animals that have been observed to show crib-biting behavior. Applicants provided no study to show how crib-biting behavior can be prevented.

4. The breadth of the claims

The scope of the claims is not commensurate with the disclosure because the specification does not teach how crib-biting is prevented.

Applicants may overcome this rejection by either deleting preventing from the affected claims or substituting minimizing for preventing in the affected claims.

4. Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 11 recites "controlling the stomach pH of an animal." How the stomach pH is controlled is not disclosed in the specification. What methods are employed in controlling the stomach pH of an animal? Does controlling stomach pH in animals involve administering an agent to the animal to control the pH? Results from the example, page 17, lines 9-12, state a relationship between crib-biting and stomach acidity and that crib-biting is an adaptive attempt to reduce stomach acidity. However, there is no written description on how stomach pH is controlled.

5. Claims 3-5, 11-23 and 28-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 3 recites the limitation "the amount" in line 2. There is insufficient antecedent basis for this limitation in the claim.

The rejection may be overcome by amending the claim to read ---... in which the fat in the composition is an amount of from...

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7. Claim 4 recites the limitation "the amount of crude fiber" in line 2. There is insufficient antecedent basis for this limitation in the claim.

The rejection may be overcome by amending the claim to read ---... in which the fiber in the composition is crude fiber and is present in an amount of from...

8. Claim 5 recites the limitation "the amount of neutral detergent" in line 2. There is insufficient antecedent basis for this limitation in the claim.

The rejection may be overcome by amending the claim to read ---... in which the fiber in the composition is a neutral detergent fiber and is present in an amount of from...---

9. Claim 8 recites the limitation "the starch" in line 2. There is insufficient antecedent basis for this limitation in the claim.

It appears from the specification, page 6, line 29, that "starch" is different from fiber and thus the claim may be amended to recite ---...in which the composition further comprises starch in an amount below 20% by weight ...---

10. Claim 11 recites the limitation "the stomach pH" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 11 is vague and indefinite because the claim does not describe how the pH is controlled. There does not appear to be method steps in claim 11, specifically the step or method of controlling stomach pH is not recited in the claim. For examination purposes, claim 11 is interpreted to be a method of treating or ameliorating animal stereotypy where the method comprises administering a composition containing an antacid to control stomach pH of the animal. This interpretation is supported by the specification, page 10, line 24 to page 11, line 2.

***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Winskill et al. (In Applied Animal Behavior Science, 1996, Vol. 48, pp 25-35).

Winskill discloses feeding horse with food composition in pelleted form and the food comprises 100 g protein, 200 g fiber, 27.5 g oil and 85 g ash in addition to feeding the horse on concentrates and “timothy hay” (pages 27 and 28). In Winskill, fiber is about 48.5% and fat is about 6.7%. Regarding claim 8, an amount of starch of below 20% reads on no amount or zero amount of starch in the composition such that the Winskill meets the limitations of the claims, where the composition of Winskill does not contain starch.

Claim 1 recites a composition that comprises fat and fiber. The presence of antacid is optional in said composition. Future intended use is not critical in a composition claim. The comprising language in claim 1 does not exclude the presence of protein and ash. Oil is considered to be a fat. Thus Winskill anticipates the claim.

13. Claims 1 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Inoue et al. (GB 2 200 027).

Inoue discloses animal feed comprising oil palm fronds that are compressed into compact form for feeding livestock including horses (page 1, lines 17-21). The compact form of the compressed oil palm fronds is a pellet of about 30 mm (3 cm) in length and 15 mm (1.5 cm) in

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diameter and Inoue states that the size and shape of the pellets may be varied for different types of animals as appropriate (page 2, lines 13-16). According to Inoue, analysis of oil palm leaflets of oil palm fronds yields in percent by weight, 54.3% water, 5.2% crude protein, 2.3% crude fat, 14.3% fibers and 3.7% rough ash, and 19.5 mg/100 g total carotene and 221 mg/100 g Vitamin E (page 5, lines 16-28). Although, Inoue does not refer to water as a pharmaceutically acceptable carrier, the analysis contains water and water is a carrier and is pharmaceutically acceptable.

Inoue's animal feed further comprises calcium and/or iron nutritional additives (claims 5 and 6).

Regarding instant claim 8, Inoue is silent or does not disclose the presence of starch in the composition from the oil palm fronds. But the amount of starch is below 20% and zero is below 20%, which means that the composition in claim 8 does not have to have starch. Also, instant claim 1 is directed to a composition comprising fat and fiber and antacid is optional, and since a future intended use is not critical in a composition claim and since the comprising language of claim 1 does not exclude other ingredients, the teachings of Inoue meet the limitations of the claim.

### ***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 2, 4, 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inoue et al. (GB 2 200 027).



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Inoue clearly teaches the composition of claims 2, 4 and 6 except that Inoue does not refer to the composition as pharmaceutical composition where water is a pharmaceutically acceptable carrier. Regarding claims 4, Inoue's generic fiber encompasses crude fiber and since Inoue discloses cutting the compressed oil palm fronds, the cut fiber encompasses chopped fiber of claims 6 and 7.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a composition comprising calcium and/or iron nutritional additives and oil palm fronds analyzed to comprise fat and fiber and protein and vitamin E and water and to refer to the composition as pharmaceutical composition since the composition comprises water, which is a pharmaceutically acceptable carrier and since the composition is administered to animals with the expectation of providing healthy stomachs to animals upon administration as disclosed on page 7 line 23 to page 8 line 1 of GB 2 200 027.

16. Claims 3-6 rejected under 35 U.S.C. 103(a) as being unpatentable over Winskill et al. (In Applied Animal Behavior Science, 1996, Vol. 48, pp 25-35).

Winskill clearly teaches the composition of the invention except that Winskill teaches 6.7% oil in the composition and the invention recites fat. Regarding claims 4-6, the generic teaching of fiber in Winskill encompasses crude and neutral detergent fiber and does not exclude chopped fiber. Since fat and oil can be used interchangeably by one of ordinary skill in the art, it would have been obvious to one of ordinary skill in the art at the time the invention was made to feed horses a composition comprising 24.2% protein, 48.5% fiber, 6.7% fat or oil and 20.6% ash in addition to concentrates and timothy hay according to Winskill since fat and oil are used interchangeably.

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17. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winskill et al. (In Applied Animal Behavior Science, 1996, Vol. 48, pp 25-35) in view of Johnson et al. (In Equine Veterinary Journal, 1998, MARCH, Vol. 30 (2) 139-143) further in view of Pagan (In Australian Equine Veterinarian, Vol. 16 (4) Summer 1998).

Winskill discloses feeding horse with food composition in pelleted form and the food comprises 100 g protein, 200 g fiber (about 48.5%), 27.5 g oil (about 6.7%) and 85 g ash in addition to feeding the horse on concentrates and “timothy hay” (pages 27 and 28). The horses in Winskill exhibited stereotypic behavior and in the abstract in Winskill it is suggested that stereotypy may be caused by the horse’s inability to express foraging behavior (lines 1 and 2 of the abstract). In Winskill’s study, the horses expressed foraging behavior when fed the feed comprising fiber and oil (fat). Winskill teaches the composition of the instant claims except that Winskill does not teach a feed composition that contains an antacid.

However, Johnson suggests a relationship between pH or acidity of the hindgut and behavioral responses (first and second paragraph, right column, last 2 lines, page 139) and specifically states that neutralizing acidity of the hindgut by administering sodium carbonate lowers the incidence of stereotypic behavior (last four lines of first paragraph, right column, page 139). Furthermore, Pagan teaches treating equine ulcers by neutralizing acidity with histamine type-2 antagonists (cimetidine and ranitidine) or proton pump inhibitors such as omeprazole or prostaglandin analogues or equine antacid such as the patented antacid Neigh-Lox (pages 160 and 161).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the composition of Winskill to treat stereotypic behavior and to incorporate

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antacid of Johnson or Pagan with the expectation of lowering or reducing the acidity of the hindgut. One having ordinary skill in the art would have been motivated to do this in order to lower the incidence of stereotypic behavior.

18. Claims 11-19, 22, 23 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (In Equine Veterinary Journal, 1998, MARCH, Vol. 30 (2) 139-143) and Winskill et al. (In Applied Animal Behavior Science, 1966, Vo. 48, pp 25-35) and further in view of Pagan (In Australian Equine Veterinarian, Vol. 16 (4) Summer 1998).

Instant claim 11 is interpreted as a method of treatment or amelioration of stereotypy, the method comprising administering a composition that contains antacid to control stomach pH of an animal for examination purposes. The method is administration.

Johnson discloses that sodium carbonate, an antacid, can be administered to stabled horses to neutralize acidity of hindgut and neutralizing the acidity lowers the incidence of stereotypic behavior (page 39, right column, first paragraph). Johnson recruits 4-10 year old male and female horses in the study where the horses were fed hay and concentrate in alternate week and one of the groups has the feed supplemented with Founderguard (page 140, left column, lines 10-20). The feed also contained crude fiber and crude protein (page 140, left column, lines 21-28). The horses were observed for grasping, wood chewing, cribbing and wind sucking (left column of page 140, lines 42 to the end). Cribbing and wind sucking are stereotypic behaviors. The result of the study is that Founderguard led to a reduction in abnormal behavior or stereotypic behavior by reducing acidosis of the hindgut. Since the horses were purchased and placed in the study, the horses have to have been weaned although the art is silent on that and examiners position is that the horses in Johnson's study encompasses the scope of recently

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weaned or weaning as recited in claim 14 or being weaned as recited in claim 22 or following weaning as recited in claim 23 or weaned as recited in claim 15. Regarding claim 13, examiner takes the position that the stomach pH of the horse is controlled before or shortly after the horse develops stereotypic behavior since the result in Johnson states that administration of Founderguard reduces abnormal behavior by controlling hindgut acidosis. Regarding claim 12, examiner's position is that Johnson's study treated the horses before the stereotypic behavior is permanent or "fixed" as recited in said claim; the examiners position is supported by applicant's admitted prior art on page 7, lines 10-17 that an animal should be treated once the stereotypic behavior is observed before the stereotypy is fixed or permanent since the animal will continue to perform the stereotypic behavior once the behavior is fixed.

Winskill discloses feeding horse with food composition in pelleted form and the food comprises 100 g protein, 200 g fiber (about 48.5%), 27.5 g oil (about 6.7%) and 85 g ash in addition to feeding the horse on concentrates and "timothy hay" (pages 27 and 28). The horses in Winskill exhibited stereotypic behavior and in the abstract in Winskill it is suggested that stereotypy may be caused by the horse's inability to express foraging behavior (lines 1 and 2 of the abstract). In Winskill's study, the horses expressed foraging behavior when fed the feed comprising fiber and oil (fat).

A combined teaching of Winskill and Johnson is a method of feeding horses with a feed that comprises fat, fiber, protein, hay and where the feed is supplemented by Founderguard for treating stereotypic behavior in animals.

Johnson and Winskill clearly teach the method of the instant claims except that the combined teaching of Johnson and Winskill does not teach administering proton pump inhibitor

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or histamine type-2 antagonist to control stomach pH, although Johnson suggests that neutralizing acidity of the hindgut with sodium carbonate lowers the incidence of stereotypic behavior.

But, Pagan teaches treating equine ulcers by neutralizing acidity with histamine type-2 antagonists (cimetidine and ranitidine) or proton pump inhibitors such as omeprazole or prostaglandin analogues or equine antacid such as the patented antacid Neigh-Lox and the above three classes of drugs inhibit gastric secretion (pages 160 and 161).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use histamine type-2 antagonists or proton pump inhibitor in the composition of Johnson, in place of the sodium carbonate suggested by Johnson, with the expectation that the histamine type-2 antagonists or proton pump inhibitor will reduce or inhibit gastric secretion.

19. Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (In Equine Veterinary Journal, 1998, MARCH, Vol. 30 (2) 139-143) and Winskill et al. (In Applied Animal Behavior Science, 1966, Vo. 48, pp 25-35) in view of Pagan (In Australian Equine Veterinarian, Vol. 16 (4) Summer 1998).

Winskill discloses feeding horse with food composition in pelleted form and the food comprises 100 g protein, 200 g fiber (about 48.5%), 27.5 g oil (about 6.7%) and 85 g ash in addition to feeding the horse on concentrates and "timothy hay" (pages 27 and 28). The horses in Winskill exhibited stereotypic behavior and in the abstract in Winskill it is suggested that stereotypy may be caused by the horse's inability to express foraging behavior (lines 1 and 2 of

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the abstract). In Winskill's study, the horses expressed foraging behavior when fed the feed comprising fiber and oil (fat).

Johnson suggests a relationship between pH or acidity of the hindgut and behavioral responses (first and second paragraph, right column, last 2 lines, page 139) and specifically states that neutralizing acidity of the hindgut by administering sodium carbonate lowers the incidence of stereotypic behavior (last four lines of first paragraph, right column, page 139).

A combined teaching of Winskill and Johnson is a method of feeding horses with a feed that comprises fat, fiber, protein, hay and where the feed is supplemented by Founderguard for treating stereotypic behavior in animals and the Founderguard controls hindgut acidosis.

The combined teaching of Winskill and Johnson teaches the method of the invention except that it does not teach treating ulcers.

But, Pagan teaches treating equine ulcers by neutralizing acidity with histamine type-2 antagonists (cimetidine and ranitidine) or proton pump inhibitors such as omeprazole or prostaglandin analogues or equine antacid such as the patented antacid Neigh-Lox (pages 160 and 161).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use histamine type-2 antagonists or proton pump inhibitor in the composition of Johnson, in place of the sodium carbonate suggested by Johnson, with the expectation that the histamine type-2 antagonists or proton pump inhibitor will treat ulcer since reducing or inhibiting gastric secretion would lead to treating ulcer.

Claims 20 and 21 directed to including fat and fiber and optionally antacid to the animals diet from birth or including the fiber diet in the feed of the lactating mother are rejected under 35


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USC 112, second paragraph. However, with regards to the claims 20 and 21, the cited prior art is silent on feeding lactating mothers and horses from birth with a diet of fat, fiber and optional antacid.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara   
Patent Examiner  
Tech. Center 1600  
February 24, 2003